

SPL Process Meeting Meeting Minutes January 15, 2014

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

New Discussion Topics:

Note: Future discussion topics with Lonnie are highlighted throughout this document in yellow.

1. New validation procedure document – available on SPL resources page.

- <http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321876.pdf>
- Please review the validation procedure and send us any questions that you have on new/changes to validation procedures. We could potentially invite Lonnie to attend and explain those changes for which we have questions.
 - Question 1: 3.1.10 indicates that the product needs to have a combination product data element specified – ie . This would affect all future SPLs.
 - This is expected to become a mandatory in the “near” future.

2. Combination products:

- New data element on SPL resources page – Combination Product Type: see list of data values.

Combination Product Types

Source: National Cancer Institute Thesaurus

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

SPL Acceptable Term	Code
Type 0: Not a Combination Product	C112160
Type 1: Convenience Kit of Co-Package	C102834
Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	C102835
Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)	C102836
Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	C102837
Type 5: Device Coated or Otherwise Combined with Biologic	C102838
Type 6: Drug/Biologic Combination	C102839
Type 7: Separate Products Requiring Cross Labeling	C102840
Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)	C102841
Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	C102842

- Melanie Benson: For classification Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) – does this mean an already approved PFS which was approved as a simple contain-closure supplement back in the 90's will now be considered under this code, or is this for product approved specifically as a combination product?

- Question 2: We need to ask Lonnie to discuss what this means.

- o This may cover all products and may highlight what is defined as a kit.
- o Does this cover only those products that cross divisions...or a single division.

Holdovers from Last Meeting

3. Is there a way to file so that the FDA knows not to disclose proprietary information on Daily Med?
(Samantha Hanagan)

HOLDOVER TO THE NEXT MEETING

4. Establishment registrations (Ken Stevenson)

Scenario

- Client A is a domestic PLD having its own label and labeler code.
- Client B is a foreign manufacturer with a domestic facility to which drug products are shipped. The foreign facility belonging to Client B is an FDA registered drug establishment but the registration is for the single foreign establishment. The domestic facility belonging to Client B is not an FDA registered facility.
- Client B foreign does the manufacturing.
- Client B US facility does the labeling.
- Client A is coordinating the manufacture of an OTC product that Client B will manufacture at its foreign facility. The product will then be shipped from Client B's foreign facility, to Client B's domestic facility. Although Client A is a PLD, this particular product belongs to Client B and will be delivered turnkey to Client A. At that point Client A will simply distribute the finished OTC. My only role in the process is assistance with SPL and Establishment Registration.

My questions are these:

1. What establishment registrations/business operations are necessary for this product to reach final distribution without issue or delay?
 - Does Client A need to register its facility? As they are currently only a PLD and have no establishment registration will they need to submit establishment registration for this scenario? Since Client A's only roles in this scenario are to coordinate the process and final distribution should they register there establishment and if so what business operations should be included?
 - How should Client B register its domestic facility for this OTC Product? What business operations? Assuming that the domestic facility already has a DUNS.
 - Will Client B need to add any additional business operations to their current FDA establishment registration for their foreign facility?
2. What submissions will be needed in order to correctly list this product so as to reach the final distributor without issue or delay?
 - By Client A?
 - o Any additional comments or information?

- By Client B?
 - o What information will be presented in the Data Elements section of the listing submission(s) and how will it be arranged?
 - o If the product is manufactured at Client B's foreign facility, shipped without being labeled and then labels are applied at Client B's domestic facility; how does this affect the establishment registrations, drug listings and the information therein?
- 3. Any additional comments or information?

Discussion:

Establishment registration:

- Client B needs a DER for both facility:
 - o Foreign: manufacturer (the US facility is the agent). Make sure that the importer (Client B US) is identified.
 - o US: labeler and packer
- Client A (PLD) does not need a DER because they are not a manufacturer.

Drug Listing:

- Client B (foreign) needs to drug list under its labeler code that as a semi-finished product "drug for further processing"
 - o This is key for importing.
- Client B (US) needs to drug list the finished product under its labeler code "OTC manufactured exclusively for PLD"
- Client A drug lists this under its own labeler code – as finished product.

5. D&B data issues

- Merck is part of a pilot program and had a number of issues. Dale sent whole file to D&B to get their help in resolving their issues.

D&B - compared all data from all sites – so that they could determine the differences.

Talked through all the issues. D&B is investigating several of their issues. They are going to talk to FDA to determine if there is some flexibility in terms of allowing differences.

Merck will not change addresses or names, but will make minor changes in addresses if the address is still consistent. Merck also needs several new DUNS numbers because the addresses didn't match up.

***Hold to next meeting. Mary Beth Wilucz will follow up to see if anyone is carrying this on.

- Has anyone had recent experience changing an address with D&B? Please share your experience (Jennifer Hinzman – Mylan)

Discussion:

- Someone has changed the address of the company, but D&B will not tell them who changed it. They thought that only an officer of the company could update it.
 - This has been brought up to D&B as an issue – and they did not give us any indication that this would change.
 - You might contact the finance department to get a contact as to who is maintaining your company's relationship/information with DnB
 - Best practices:
 - o Customer service is hard to work with.
 - o Try to get a specific DnB representative to facilitate making the changes.
6. New FEI number: I was wondering if anyone in the group has had the opportunity to request a new FEI number for a site, and exactly what the process is. I have heard different stories and would like to know if anyone has actually done it since SPL has been in use.

Charisse Kasser was involved with writing the new guidance. The FEI number will not go away, at least in the near future. At any event, the FEI will be used internally at FDA in their computer systems. Many FDA ORA systems use the FEI numbers, so the FEI number will stay.

Per Pat (Lilly) and Dragan (Abbott): We submitted the DER without the FEI number. Companies will get the FEI number from the local office – in the inspection report that comes from the FDA.

Per Howard (DCLabs): If you don't get the FEI numbers within 60-90 days, follow up with the eDRLS office.

Per Kathy Lins: For GDUFA, they contacted FDA by email requesting an FEI for a new facility. They were able to get their FEI number within a day. This may be recent because it is required for GDUFA reporting.

Walk ins:

7. Vicki Vos (Baxter): I still have issues with the Revised Date at the end of the Highlights section within a PLR as to how this is determined. As discussed before in these meetings I was under the impression that this is now being pulled from the most recent update to sections 1 – 17, as per the attached copy of the meeting minutes:

Changes include the following (additional information added per followup with Lonnie:

- 4) Rendering of most recent highlights text revision date excluding Data Elements Section and all sections past section 17.
 - highlights revision date no longer being pulled from effective time – it's pulled from whatever section was changed most recently
 - The highlights date will pick up latest revision date in sections 1-17.

Question: In the new validation procedure if I am reading this correctly on pages 22-23 under "Highlights and labeling boilerplate items included" it states that the revised date is taken from the effective time. My question, is when I think of "Effective Time" that is the date that is entered into the "Labeler, Registrant, and Establishment Information" under "Effective Date". So based off of this, it is still being pulled from the Effective Time?

Any help in understanding where this date is being pulled from so that I can communicate this out correctly is greatly appreciated.

Discussion:

- Question for Lonnie: Section 2.2.4. Is this working as previously discussed. Was there an oversight in the validation document – ie t
- FDA stylesheet pulls the date from Sections 1-17
- DailyMed just switched their stylesheet over to using Section 1-17

8. Chad (Reed): There is a new validation procedure that checks that the ingredients match previous submissions that use an application numbers.
 - Real reason behind this – several companies are submitting under the same application number but using different ingredients.
 - What error is this trying to catch? They want to make sure that all companies manufacturing product under the same application are reporting the same data/ingredients for the application (relabelers, manufacturers, etc) Consistency.
 - What happens if there are multiple records already on Daily Med that have this error. Which one will be used as the primary record?
 - Question for Lonnie: Validation section number: 3.1.7.26. Page 43. Newly implemented that will improve quality of data on Daily Med.
 - Kathy Lins: One of their products is used as a component in 101 kits—from numerous other manufacturers. Thus, the validation procedure will make sure that all of the kits report the active ingredient consistently with what is reported by their application drug listing.

Announcements: